IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Osamu OKUDA et al.

Title: METHODS FOR TREATING INTERLEUKIN-6 RELATED DISEASES

Appl. No.: Unassigned

Filing Date: Herewith

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

RELEVANCE OF EACH DOCUMENT

All of the documents listed on the attached PTO/SB/08 were cited as being relevant during the prosecution of the corresponding International application. Copies of the documents are not being provided since copies should have been provided directly by WIPO under an exchange program between the PTO, the EPO and the JPO. A copy of the International Search Report is attached setting forth the portion of each document considered relevant by the examiner.

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date October 24, 2005

By _____ 39,310

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MODIFIED PTO/SB/08 (08-00)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: October 24, 2005

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Sheet 1 of 2

Complete if Known

Application Number	Unassigned
Filing Date	Herewith
First Named Inventor	Osamu OKUDA
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	053466-0409

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	U.S. Patent Document Number	U.S. Patent Document Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	5,210,075		Scholz et al.	05/11/1993	
	A2	6,270,766	B1	Feldman et al.	08/07/2001	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Office[3]	Number[4]	Kind Code[5] (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	A3	EP	1 074 268	A1	Chugai Seiyaku Kabushiki Kaisha and Tadamitsu KISHIMOTO	02/07/2001		
	A4	PCT	WO 97/10338		Chiron Corporation	03/20/1997		
	A5	PCT	WO 99/64070		Ophidian Pharmaceuticals, Inc.	12/16/1999		
	A6	PCT	WO 2004/039826	A1	Centocor, Inc.	05/13/2004		

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[6]
	A7	BAERT, Filip et al, "Influence of Immunogenicity on the Long-Term Efficacy of Infliximab in Crohn's Disease", NEW ENGLAND JOURNAL OF MEDICINE, February 2003, Vol. 348, No. 7, pgs. 601-608.	
	A8	CHOY, E. H. S. et al, "Therapeutic Benefit of Blocking Interleukin-6 Activity With an Anti-Interleukin-6 Receptor Monoclonal Antibody in Rheumatoid Arthritis: A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation Trial", ARTHRITIS AND RHEUMATISM, December 2002, Vol. 46, No. 12, pgs. 3143-3150.	
	A9	ITO, Hiroaki et al., "A Pilot Randomized Trial of a Human Anti-Interleukin-6 Receptor Monoclonal Antibody in Active Crohn's Disease", GASTROENTEROLOGY, April 2004, Vol. 126,. No. 4, pgs. 989-996.	
	A10	MAINI & CHARISMA STUDY GROUP, "A Double-Blind, Parallel Group, Controlled, Dose Ranging Study of the Safety, Tolerability, Phamacokinetics and Efficacy of Repeat Doses of MRA Given Alone or in Combination With Methotrexate in Patients With Rheumatoid Arthritis", ABSTRACT OF PRESENTATION AT EULAR, June 2003, 2 pages.	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number. [2]See attached Kinds of U.S. Patent Documents. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 2

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First Named Inventor	Osamu OKUDA
Group Art Unit	Unassigned
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Attorney Docket Number	053466-0409

NON PATENT LITERATURE DOCUMENTS

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	A11	MAINI, Ravinder et al., "Therapeutic Efficacy of Multple Intravenous Infusions of Anti-Tumor Necrosis Factor α Monoclonal Antibody Combined with Low-Dose Weekly Methotrexate in Rheumatoid Arthritis", ARTHRITIS AND RHEUMATISM, September 1998, Vol. 41, No. 9, pgs. 1552-1563.	
	A12	NISHIMOTO, N. et al., "Toxicity, Pharmacokinetics, and Dose-Finding Study of Repetitive Treatment with the Humanized Anti-Interleukin 6 Receptor Antibody MRA in Rheumatoid Arthritis. Phase I/II Clinical Study", JOURNAL OF RHEUMATOLOGY, Vol. 30, No. 7, July 2003, pgs. 1426-1435.	
	A13	NISHIMOTO, Norihiro et al., "Safety and Efficacy of Repetitive Treatment with Humanized Anti-Interleukin-6 Receptor Antibody (MRA) in Rheumatoid Arthritis", ARTHRITIS AND RHEUMATISM, 2002, Vol. 44, No. S9-191, pg. S84, abstract only.	
	A14	NISHIMOTO, Norihito et al, "The Long-term Safety and Efficacy of Humanized Anti-Interleukin-6 Receptor Monoclonal Antibody, MRA in Multicentric Castelman's Disease", DATABASE BIOSIS "Online BIOSCIENCES INFORMATION SERVICE, November 2003, 1 page.	
	A15	WAGNER, C. L., et al., "Consequences of Immunogenicity to the Therepeutic Monoclonal Antibodies ReoPro® and Remicade®", IMMUNOGENICITY OF THERAPEUTIC BIOLOGICAL PRODUCTS, 2003, pgs. 37-53.	

Examiner Signature		Date Considered	

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